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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/960,477	09/24/2001	Yuji Ishihara	2001-1276	6807

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WASHINGTON, DC 20006-1021

EXAMINER
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TRUONG, TAMTHOM NGO

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 06/30/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/960,477

Applicant(s)

ISHIHARA ET AL.

Examiner

Tamthom N. Truong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13, 17, 18, 20, 26-30, and 34 is/are pending in the application.
- 4a) Of the above claim(s) 14-16, 19, 21-25, and 31-33 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 26-30, and 34 is/are allowed.
- 6) ☒ Claim(s) 1-13 and 18 is/are rejected.
- 7) ☒ Claim(s) 17 and 20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 09/787,288.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### DETAILED ACTION

Applicant's election with traverse of Group I in Paper No. 10 is acknowledged. The traversal is on the ground(s) that group I is unfairly narrow. This is not found persuasive because the on-line search for the generic peri-fused tricycle in claim 4 would yield a large number of hits. Group II is a tricycle; however, it is an ortho-fused tricycle, and is patentably distinct. A search for group I does not yield references that would read on group II.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-13, 17, 18, 20, 26-30, and 34 are considered herein while claims 14-16, 19, 21-25, and 31-33 are withdrawn from consideration as being drawn to non-elected subject matter.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-3, 6-9, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by **Kawakita et. al.** (US 5,864,039). On column 18, Kawakita et. al. discloses two compounds (on lines 32 and 33) that are embraced the formula in claims 2 and 3 with the following substituents:

- i. Ar is an phenyl group;
- ii. R and R' are hydrogen;

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iii. Y is a substituted nitrogen-containing heterocyclic group.

Note, the disclosed compounds belong to the subgenus of (I-4) {on column 16} with A<sup>6</sup> as a heterocyclic group containing B<sup>5</sup>. Variable B<sup>5</sup> is defined as X<sup>4</sup>-R<sup>13</sup>, which corresponds to Ar-C(=O). The disclosed "benzamide" portion corresponds to the substituent on the instant variable Y. The pharmaceutical composition is taught on column 76, thus the reference reads on the instant composition claims. Because Kawakita et. al. use their compounds to treat "dysuria" (see column 76, line 16), it is understood that said compounds can improve "excretory potency of the urinary bladder". Thus, the reference reads on all limitations of the instant composition claims.

2. Claims 1 and 18 are rejected under 35 U.S.C. 102(b) as being inherently anticipated by **Ashani et. al.** (US 4,472,320). The reference's compound of formula III treats bladder dysfunction. Thus, a pharmaceutical composition to improve "excretory potency of the urinary bladder" is inherently suggested. Thus, the composition of claims 1 and 18 are anticipated.

3. Claims 1-13, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by **Grotto et. al.** (US 5,527,800). On columns 78 and 79 of US'800, Tables 22, and 23 disclose many per-fused tricyclic compounds that have acetylcholinesterase inhibitory effect, and read on the compounds claimed herein. The pharmaceutical composition of said compounds is disclosed on column 168. Although the instant composition claims recite an intended use of "improving excretory potency of the urinary bladder", such a preamble does not have patentable weight in a pharmaceutical composition claim (see *In re Tounimen*, 213 USPQ 89). Thus, the teaching of Grotto et. al. still anticipates the pharmaceutical composition claimed herein.

### ***Double Patenting***

The **nonstatutory double patenting** rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 5,527,800. Although the conflicting claims are not identical, they are not patentably distinct from each other because the pharmaceutical composition claimed herein embraces the pharmaceutical composition claimed in US'800. Although the instant pharmaceutical composition claims recite an intended use of "improving excretory potency of the urinary bladder", said preamble does not have patentable weight. Thus, it is obvious to make a pharmaceutical composition claimed herein in view of the teaching of Grotto et. al. (US'800). Again, see *In re Tounimen*, 213 USPQ 89 regarding different intended use in a pharmaceutical composition.

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***Claim Objections***

5. Claims 17 and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


***Allowable Subject Matter***

6. Claims 26-30, and 34, the references of record do not teach or suggest species recited in said claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 703-305-4485. The examiner can normally be reached on M-F (9:30-5:00) & every Saturday morning (starting from 4-7-03).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

  
**Tamthom N. Truong**  
**Examiner**  
**Art Unit 1624**

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June 27, 2003